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FDA Docket Clerk
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

Docket No. 98N-1038

Dear Sir or Madam:

The National Restaurant Association, representing more than 37,000 members and 175,000 restaurant outlets, would like to comment on potential revisions of the current labeling requirements for irradiated foods. The restaurant industry applauds the government's approval of irradiation, or "cold pasteurization" as one technology to control microorganisms in meats and other foods. As such, the irradiation process itself is not mandated, but rather is recognized for its potentially beneficial impact on public health, similar to the pasteurization of milk.

The National Restaurant Association is strongly committed to serving safe food, and is working as a partner to educate the public about important food safety messages. However, we believe that FDA should not require labeling of irradiated ingredients or foods in their entirety, particularly on restaurant menus. Mandatory labeling of irradiated foods does not enhance consumer acceptance of this technology, nor does it convey adequate information about the process and its benefits. Consistent with effective implementation of this new technology is the need to educate consumers about the potential benefit of cold pasteurization and to address the misinformation surrounding this process.

The current rules related to the labeling of foods treated with ionizing radiation call for the inclusion of the radura logo and a disclosure statement. We believe the current requirement works in opposition to effective consumer education on this issue. We support the petition submitted by the National Food Processors Association which states that the current required labeling of cold pasteurized foods "causes consumer concern about a non-existent hazard, at the expense of discouraging a process that can mitigate very real safety hazards." Therefore, FDA should consider removing the current labeling requirements for irradiated foods.

The National Restaurant Association would like to respond to the 15 questions specifically outlined in the proposal. The terms "irradiation" and "cold pasteurization" are used interchangeably throughout these comments.

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1. Does the current radiation disclosure statement convey meaningful information to consumers in a truthful and nonmisleading manner?

No, the current radiation disclosure statement does not convey meaningful information to consumers.

Results from focus group research indicate that many consumers have heard about food irradiation from newspapers and television, but they do not know enough about the irradiation process to thoroughly understand it. They are fearful of the word "radiation" (Resurreccion and Galvez, 1999).

Other strategies for providing consumers with meaningful information about irradiated foods should be implemented, such as public service announcements, brochures and handouts.

2. How do consumers perceive the current radiation disclosure statement—as informational, as a warning, or as something else?

It is our belief that consumers perceive the disclosure statement, "treated with X-radiation" or "treated with electron beam radiation," as a warning.

In one study, a military population was divided into groups to assess consumers' concerns and awareness of irradiated foods (Schutz and Cardello, 1997). The treatment group, which viewed an informational video, which contained a clearly positive perspective on food irradiation, had significantly less concern and was more likely to consume irradiated foods. When only basic information was presented, i.e., a disclosure statement and the radura symbol, it was clear there was no significant impact on reducing concern level or on willingness to purchase irradiated foods.

Increasing awareness of the irradiation process should be undertaken with a long-term educational approach, since there appears to be a positive synergism between a video presentation plus statements that include positive, credible information about the safety of irradiated foods (Schutz and Cardello, 1997).

3. Does the wording of the current radiation disclosure statement cause "inappropriate anxiety" among consumers? What are examples of "inappropriate anxiety"?

Yes, the wording of the current radiation disclosure statement does cause inappropriate anxiety.

Many consumers have misperceptions about the process of cold pasteurization. A negative image may be due in part to fear and confusion about Three Mile Island-type incidents. In addition, there is a general lack of knowledge about the use of irradiation technology for spices, sterilization of medical equipment, and the term "radiation" itself as a simple source of heat. There has also been intentional misrepresentation of proven facts from groups with specific agendas. Examples of inappropriate anxiety include the association of "radiation"

with cancer radiation therapy and "people glowing in the dark." (Resurreccion and Galvez, 1999). The International Food Information Council (IFIC) also determined from focus group research that some consumers associated the process with cancer and x-rays (IFIC, 1998).

Elimination of this required labeling would do more to facilitate the health benefits and use of this process than any other action.

4. *What specific alternate wording for a radiation disclosure statement would convey meaningful information to consumers, in a truthful and nonmisleading manner, and in a more accurate or less threatening way than the current wording?*

Disclosure statements on restaurant menus inappropriately put operators in the position of answering technical and health and safety questions that they are unqualified to answer.

Consumers want to be informed about irradiation, however, they want the information from knowledgeable sources. When consumers were asked about naming the irradiation process, they indicated that a statement that uses the term "cold pasteurization" instead of the terms "radiation" or "irradiation", augmented with a statement of benefit would be preferable to the currently required statement, "Treated with radiation" (Resurreccion and Galvez, 1999). The statement, "Treated by cold pasteurization to control foodborne bacteria" is more effective for enhancing consumers' understanding of the treatment. This finding was also verified by consumer attitude research conducted by the International Food Information Council, *Consumer Attitudes Toward Food Irradiation, Analytical Report* (IFIC, 1998). The term "cold pasteurization" was by far the most popular of a series of names tested to describe the process.

Disclosure statements on menus are misinterpreted, inappropriate and generally unwanted by the majority of consumers. We generally recommend that consumer education be carried out by competent irradiation or health professionals.

5. *Would consumers be misled by the absence of a radiation disclosure statement in the labeling of irradiated foods? Are consumers misled by the presence of such a statement?*

No, consumers would not be misled by the absence of a radiation disclosure statement. However, they are misled by the presence of such a statement.

It has been found that consumers with lower education and income levels tend to be more concerned about the effects of irradiation (Lusk, Fox, and McIlvain, 1999). It has also been shown that when only basic information, i.e. a disclosure statement and radura were presented, it was clear there was no significant impact on reducing consumers' concerns or their willingness to purchase irradiated foods (Schutz and Cardello, 1997).

Long-term consumer education may improve consumer attitudes; however, the type of education is essential. Schutz and Cardello (1997) indicated that there appears to be a positive synergism between a video presentation plus statements that include positive, credible information about the safety of irradiated foods from recognized professionals.

Alternative wording that conveys the purpose and benefit of irradiation should be used. Cold pasteurization was judged as appropriate and meaningful by consumers. This term is not misleading and it allows the consumer to compare irradiation to more familiar applications of pasteurization.

6. *With respect to foods containing irradiated ingredients, are consumers misled by the absence of a radiation disclosure statement? Would consumers be misled by the presence of such a statement?*

No, consumers would not be misled by the absence of a disclosure statement.

One reason why consumers would be misled by the presence of a statement is because the government has considered irradiation to be a food additive. Participants in focus group research to assess consumer attitudes and behavior regarding the purchase of irradiated beef preferred that irradiation be presented as a process rather than as an additive (Resurreccion and Galvez, 1999). Their perception of an additive was "something that is added to the food and stays there." A process is something that is done to the food and "nothing of it is left in or on the food."

Because the irradiation of foods is a process and not an additive, nothing is imparted to the food. FDA should not require labeling, as it does not require labeling for other processes.

7. *What is the level of direct consumer experience with irradiated foods that are labeled as such?*

Consumers recognize the need for cold pasteurization, particularly for meats and fish, as a means to control microbial growth.

People who have purchased irradiated food generally trust the industry and the scientific community to make correct judgments. Government agencies such as the FDA/USDA are not viewed as powerful endorsement bodies (Bruhn, 1995). Consumers either believe the label is a hazard warning, or they associate irradiation with improved safety. Therefore, FDA's current irradiation label is misleading. In the case of irradiated spices, although they have been used by the food processing industry because labeling is not required, they have not been sold on retail shelves because producers believe the irradiation label will hurt sales. In fact, some believe that customers are so concerned with irradiation that they label their product in reverse, "not irradiated" (Food Labeling and Nutrition News, 1999).

There is some indication that consumers view cold pasteurization of foods favorably under certain circumstances. Research sponsored in part by the National Restaurant Association showed that the number one reason for purchasing irradiated product is to kill disease-causing bacteria, *A Study of Consumer Attitudes Toward Irradiation* (FMI, 1998). In general, most consumers believe that cold pasteurization would lower the risk of coming down with food poisoning at restaurants – at least to some extent. They also believe that it is appropriate, at least to some degree, to incorporate irradiated foods in hospitals, fast food restaurants, tableservice restaurants, and grocery store delis. Sixty percent of the consumers surveyed said that they would like to know more about the impact of irradiation on bacteria and nutrition. Bruhn (1998) has published market experiences of consumers to irradiated foods, and reported that irradiation is more accepted in up-scale markets. She stresses that conventional consumer concern about irradiation could be decreased through educational efforts.

We believe market forces will tend to push manufacturers in the direction of voluntary informative labeling for improved food safety reasons. Restaurant operators should be exempt from menu labeling of irradiated foods due to the extensive item mixing and daily change of food products in the restaurant environment.

8. *What is the effect of the current required labeling on the use of irradiation? Does the current required labeling discourage the use of irradiation?*

The current labeling regulations contribute to consumers' concerns that the food supply may be less safe, nutritious, and convenient than they expect.

The effect of the current required labeling is negative on consumers' perceptions because it cannot adequately convey necessary information about the benefits. The overall effect is to discourage the use of irradiation.

Cold pasteurization is a process to make food safe like many others and therefore, it is inappropriate for FDA to require any special labeling for meat and poultry products in their entirety, or multi-ingredient products that may be contained in a menu item.

9. *What do consumers understand to be the effect of irradiation on food? For example, what do consumers understand about the effect of irradiation on the numbers of harmful microorganisms in or on food?*

Many consumers have a positive view of irradiation, particularly when their concern for food safety is high.

The research sponsored in part by the National Restaurant Association showed that more than 80% of consumers wanted to know about irradiation's effect on the elimination of harmful bacteria and its impact on nutrition. Killing disease-causing bacteria stood out as the most important reason for buying irradiated foods, with three-quarters of the respondents saying this was a very important reason. In terms of lowering the risk of food poisoning in restaurants, hamburgers, raw fish, and shellfish were the products consumers felt would benefit most from irradiation. Although many consumers understand the effect of irradiation to be positive, they want information on the effect of long term consumption, the nutritional value, the use in other countries, and the impact of the irradiation facility on the community (Bruhn, 1998).

Consumers do not gain greater understanding of the food safety benefits from the current radura symbol and disclosure statement requirements. This requirement should be eliminated and replaced by a credible long-term information and education program.

10. *Do consumers perceive the radura logo as informational, as a warning, or as something else?*

Consumers perceive the radura logo as a warning.

Dr. Christine Bruhn, a researcher at the University of California at Davis who has studied communication strategies for irradiated food has indicated that if consumers receive an effective educational program, consumers may prefer the safety of irradiated foods (Bruhn, 1995). However, labeling of restaurant foods is not an effective strategy for communicating information that will instill consumer confidence. Consumers have less confidence in the credibility of government information compared to that from health professionals.

FDA should exempt restaurants from the radura requirement. It is generally inappropriate and will misinform consumers more than it informs.

11. *Do consumers understand the logo to mean that a food has been irradiated?*

Consumers who have not been informed about the cold pasteurization process do not understand the intended meaning of the radura logo.

Focus group research conducted by IFIC showed that the radura symbol itself was considered appealing and pleasant. However, most consumers agreed that the radura would be too misleading or vague to stand alone on a product. An uninformed individual may think it was a brand. The three sources consumers trust most are medical organizations, health professionals, and university experts. Because the majority of consumers have not been fully informed about the benefits of cold pasteurization, it is inappropriate to place a government mandated symbol on restaurant menus.

A broad-based educational program is needed to inform the public of the advantages of this technology. The radura symbol should be used in conjunction with any educational program, but it is not sufficiently recognized to stand alone as an indication of irradiation treatment.

12. Do consumers perceive the radura logo as informational, as a warning, or as something else?

Consumers perceive the radura logo as a warning.

Dr. Bruhn has reported that the most important information to consumers is irradiated food's record of safety and wholesomeness, that the process destroys bacteria and protects against foodborne illness, and that irradiation is endorsed for safety by health authorities (Bruhn, 1998).

Consumers expect processors and retailers to provide safe food. They also indicate that they evaluate the credibility of a message by the credibility of the person conveying the message. Because cold pasteurization is endorsed by the American Medical Association, the American Dietetic Association, the American Veterinary Medical Association, the Institute of Food Technologists, World Health Association, and others, we believe it is inappropriate to mandate labeling of this process.

Our recommendation is to eliminate the radura symbol and include alternative wording for the disclosure statement on processed retail foods. The term "cold pasteurization" should be used in place of "irradiation." We advise against menu labeling of irradiated foods.

13. Should any requirement for a radiation disclosure statement expire at a specified date in the future?

The market response to irradiated foods has been positive, therefore the labeling of irradiated food is unnecessary and counterproductive to effective education about the process and its benefits.

In general, researchers have found a positive correlation between educational level and acceptance of irradiation. Those with less education tend to view irradiation as a more serious problem and had more concerns (Lusk, Fox, and McIlvain, 1999). Given the known impact education and communication strategies can have on changing consumers' attitudes toward cold pasteurization, we suggest the following:

- A disclosure statement that describes the process and confers the benefits on a stand-alone basis is preferable to use of the radura symbol with the statement, "Treated with Irradiation".
- If a refined disclosure statement is accepted, it would be appropriate to have a specified expiration date in the future for the statement.

FDA should eliminate the labeling requirements at this time to prevent further confusion or boycotts of irradiated products. If the current requirements are maintained or revised, however, an expiration based on consumer understanding and acceptance should be adopted.

14. If so, on what criteria should the expiration be based?

Consumer acceptance of cold pasteurized foods will become apparent through research on attitudes and awareness as well as market response.

There are clear indications that educated consumers are ready to purchase cold pasteurized foods, and in many cases are willing to absorb the cost. More than 60% of consumers considered cold pasteurization to be "very appropriate" in fast food restaurants and hospitals (FMI, 1998). In addition, nearly four in 10 parents say they are very likely to buy irradiated products for their children; nearly one-third of all adults say they would buy the irradiated product for themselves. These kind of statistics will provide an indication of how quickly consumer confidence is growing as well as how consumers prefer to be informed.

Voluntary labeling should be permitted should a restaurant wish to indicate an added level of safety.

15. If the expiration of labeling requirements for irradiated foods is to be based on consumer familiarity with the radura logo and understanding of its meaning, what evidence of familiarity and understanding would be sufficient to allow these requirements to expire?

The radura logo does not and never has aided with consumer understanding of the cold pasteurization process. The use of the logo has generally resulted in confusion, causing consumers to boycott particular irradiated foods. Therefore we do not support the radura or the disclosure requirements as they currently exist.

Due to the persistent consumer confusion regarding FDA's irradiation labeling requirements, FDA should consider elimination of the radura and disclosure requirements all together.

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In conclusion, we hope to avoid the perception that federally mandated labeling can somehow properly educate consumers and improve public understanding of a very complex process. Educational efforts should be long-term and come from all credible sectors, including the federal government, health professionals, universities, and the food safety professionals. As public awareness and acceptance of the cold pasteurization process grows, consumers will know that cold pasteurization is not an additive, but a new process technology that can destroy microorganisms, which cause foodborne illness.

We are deeply committed to assuring food safety and will continuously strive to provide the safest food products possible to our customers. To this end, we have taken substantive steps to improve food safety regulations, education and the safety of foods served in restaurants. We look forward to working with FDA and USDA in the future towards our common goal of improved safety.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve S. Grover". The signature is fluid and cursive, with a large initial "S" and "G".

Steven F. Grover, R.E.H.S.
Vice President for Technical Services, Public Health and Safety

Enclosures (9 references)

cc: Herman Cain, CEO & President, National Restaurant Association
Stephen Caldeira, President & COO, NRA Educational Foundation
John Farquharson, President, International Food Safety Council

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